



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/589,532

11/06/2006

Michael Noble

620-452

8708

23117 7590 08/06/2008
NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

GAWORECKI, MARK R

ART UNIT

PAPER NUMBER

2884

MAIL DATE

DELIVERY MODE

08/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,532	Applicant(s) NOBLE, MICHAEL	
	Examiner MARK R. GAWORECKI	Art Unit 2884	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-14, 20-31 and 35-41 is/are allowed.
- 6) ☒ Claim(s) 15-17 and 32-34 is/are rejected.
- 7) ☒ Claim(s) 18 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/16/06, 9/25/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because an abstract may not exceed 150 words in length. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Burd *et al.* (5,304,348).

With respect to claim 15, Burd shows a device for measuring an analyte in a fluid (column 2, lines 36-41), the device including a flow path for the fluid (various passages and chambers, column 7, lines 22-38), a predetermined amount of calibration analyte arranged on the path such that the calibration analyte mixes with the fluid that passes it to form a calibration sample (from mixing chamber, column 7, lines 52-68), a first detector means for detecting a level of an analyte (optical analysis, column 8, lines 16-49), and a second detector means for detecting the calibration analyte (measurement of dilutant, column 8, lines 1-10).

With respect to claim 16, Burd teaches the calibration analyte to be a substance not normally present in the fluid (column 7, lines 39-68).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd.

With further respect to claim 32, as applied above, Burd teaches using the calibration analyte as a reference during optical analysis of the fluid (column 8, lines 1-49). It would have been obvious to one having ordinary skill in the art when the invention was made that depending on the type of calibration analyte added to the fluid, the characteristics of said fluid would be substantially changed, in terms of dilution or other properties, wherein the results would have to be adjusted accordingly, depending on the property being tested.

With respect to claim 33, Burd teaches the calibration analyte to be a substance not normally present in the fluid (column 7, lines 39-68).

6. Claims 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd, in view of Sage (2003/0143746).

With respect to claims 17 and 34, Burd, as applied above, does not show the use of the claimed enzyme materials as a calibration analyte. However, Sage discloses a similar system in which an enzyme is mixed with blood and the concentration of glucose is measured (paragraph [0028]). It would have been

obvious to one having ordinary skill in the art at the time the invention was made to use any relevant enzymes or reactants corresponding to the constituent or analyte being measured by the device.

Allowable Subject Matter

7. Claims 1-14, 20-31, and 35-41 are allowed.
8. Claims 18 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
9. The following is a statement of reasons for the indication of allowable subject matter:

With respect to claims 1 and 25, Burd, as applied above, fails to show detecting respective analyte levels in an unadulterated sample of the fluid and in the calibration sample. Burd only shows measuring a mixed sample for both an analyte and a calibration analyte (see above). Further, Sage only shows the measurement of a mixed sample for a particular analyte (paragraph [0031]), but does not show using the same or different detectors for measuring mixed fluids as well as an unadulterated sample.

Claims 2-14, 20-24, 26-31, and 35-41 are allowable for reasons of dependency upon claims 1 and 25.

With respect to claims 17 and 34, Burd, as applied above, does not show the use of a substrate of the enzyme class of oxidoreductases acting on the CH-

OH group of donors with oxygen as an acceptor or a substrate of a synthetic enzyme such as a catalytic antibody.

With respect to claims 18 and 19, Burd, as applied above, does not specifically show the location or orientation of the detection means for measuring the calibration analyte or the fluid containing the analyte to be measured.

However, Figure 1 appears to show the cuvettes (24) used to optically measure the analyte to be used in a measurement external to the device and thus not along a path with the means for measuring the calibration analyte (column 8, lines 1-10). Further, Sage does not show using two different detectors arranged on a channel of a flow path for measuring mixed fluids as well as an unadulterated sample.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK R. GAWORECKI whose telephone number is (571)272-8540. The examiner can normally be reached on Tuesday through Friday, 6:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Porta can be reached on (571) 272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 2884

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MG/

30 July 2008

/David P. Porta/

Supervisory Patent Examiner, Art Unit 2884